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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/670,106	09/26/00	SLEATH	P VPISW002CON

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EXAMINER	
DELACROIX MUIRHEI, C	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/670,106	SLEATH et al.
Examiner	**Art Unit**
Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *July 9, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above, claim(s) *1-19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *20-49* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/Restriction

1. Applicant's election of Group II, claims 20-49 in the paper received Jul. 9, 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-19 are withdrawn from consideration.

Priority

PLEASE NOTE, in order for Applicant to properly perfect claim for domestic priority, Applicant must amend the first paragraph of the specification to include reference to the prior applications.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Objections

3. Claim 49 is objected to because of the following informalities: in claim 49, line 2, the "CF_2F" in "Boc-Asp-CF_2F" should read --CH_2F--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 43-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed method is drawn to preventing and treating autoimmune disease in a mammal comprising administering an effective amount of the claimed peptide compounds; however, the specification, while being enabling for treatment of autoimmune disease, does provide enablement for the prevention of autoimmune

diseases. The specification is enabled for the production of said compounds as well as the modes of administration necessary to treat individuals suffering from an autoimmune disease; however, there is no explanation as to how said compounds are used to prevent autoimmune diseases in an individual, i.e factors such as identification of individuals susceptible to autoimmune diseases, effective amounts or modes of administration that would successfully prevent the autoimmune disease in the individual from occurring. Applicant's specification states, overall, that the compounds of the invention are actually used to "treat" autoimmune disease in an individual. Please see page 10, lines 5-7 and page 40, line 8.

Cancellation of the limitation "preventing" would eliminate this rejection.

5. Claims 28 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28, substituent "Z" is defined; however, there is no substituent "Z" in the claimed formula.

In claim 43, at line 2, the phrase "an autoimmune disease" is vague and indefinite because the metes and bounds of said phrase are unascertainable. Even in view of the specification, one of ordinary skill in the art can't reasonably ascertain the autoimmune diseases encompassed by said phrase.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 20-25 and 28-32 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 5,756,465. This is a double patenting rejection.

The claims of the instant invention and the claims of USPN '465 are identical in scope.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 20-27, 28-34, 49 are rejected under the judicially created doctrine of double patenting over claims 1-11 of U. S. Patent No. 5,756,465 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an inhibitor compound comprising an amino acid sequence of from 1-5 amino acid residues having an N-terminal blocking group and a C-terminal Asp connected to an electronegative leaving group, wherein said inhibitor compound has a defined formula, as claimed, and further wherein preferred embodiments of said compounds have Q2 as being one amino acid, such as His, Phe, Pro or Tyr. Please refer to the claims and col. 18, lines 50-51 of USPN '465

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 20-49 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9305071 ('071).

WO '071 discloses inhibitor compounds comprising an amino acid sequence of from 1 to about 5 amino acid residues having an N-terminal blocking group and a C-terminal Asp residue connected to an electronegative leaving group, wherein the amino acid sequence corresponds to at least a portion of the sequence Ala-Tyr-Val-His-Asp. WO '071 additionally disclose the formula Z-Q2-Asp-Q1, wherein Z is an N-terminal blocking group, Q2 is 0 to about 4 amino acids such that the sequence Q2-Asp corresponds to at least a portion of the sequence Ala-Tyr-Val-His-Asp, Q1 is an electronegative leaving group, such as an aldehyde, a diazoalkyl ketone or a haloalkyl ketone. In preferred embodiments, Z is C1-C6 alkyl, benzyl, acetyl, C1-C6 alkoxycarbonyl, benzyloxycarbonyl or C1-C6 alkyl carbonyl and Q2 is 1 amino acid, preferably, His, Phe, Pro, Tyr.

Furthermore, WO '071 discloses pharmaceutical compositions of said compounds and methods of using said compounds to inhibit IL-1β protease activity and is also useful for treating inflammation or an autoimmune disease. Please refer to page 28, lines 10-18; page 30, lines 27-35 to page 31, line 20; page 33, lines 20-35; page 34, lines 1-8; claim 14.

12. Claims 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Thornberry et al.

Thornberry discloses the compound N-acetyl-L-tyrosyl-L-valyl-N-[1-(carboxymethyl)-3-diazo-2-oxopropyl]-L-alaninamide. Please refer to the abstract and structure submitted herewith.

13. Claims 20-49 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9115577 ('577).

WO '577 discloses inhibitor compounds comprising an amino acid sequence of from 1 to about 5 amino acid residues having an N-terminal blocking group and a C-terminal Asp residue connected to an electronegative leaving group, wherein the amino acid sequence corresponds to at least a portion of the sequence Ala-Tyr-Val-His-Asp. WO '071 additionally disclose the formula Z-Q2-Asp-Q1, wherein Z is an N-terminal blocking group, Q2 is 0 to about 4 amino acids such that the sequence Q2-Asp corresponds to at least a portion of the sequence Ala-Tyr-Val-His-Asp, Q1 is an electronegative leaving group, such as an aldehyde, a diazoalkyl ketone or a haloalkyl ketone. In preferred embodiments, Z is C1-C6 alkyl, benzyl,

acetyl, C1-C6 alkoxycarbonyl, benzyloxycarbonyl or C1-C6 alkyl carbonyl and Q2 is 1 amino acid, preferably, His, Phe, Pro, Tyr.

Furthermore, WO '071 discloses pharmaceutical compositions of said compounds and methods of using said compounds to inhibit IL-1β protease activity and is also useful for treating inflammation or an autoimmune disease. Kindly refer to pages 9-11.

14. Claims 20-25, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal et al.

Rosenthal discloses the compound 3-[[(1,1-dimethylethoxy)carbonyl]amino]-5-fluoro-4-oxo-pentanoic acid. Please refer to the abstract and structure attached herewith.

Please note: all references relied upon have been cited previously in parent application 09/039,657.

Conclusion

Claims 20-49 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

July 24, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600